

**Variance Committee Report of June 17, 2020
For Board Meeting of July 1, 2020
9:00 a.m. in Conference Room C**

Attendees: Amy Paradis, Mary Phipps, Ame Carlson, Michele Mattila, Jill Phillips, Kelly Hadsall, Blair Miller, Kristi Gullickson, Rachel Root, Jessica Swearingen, Alison Sinclair, David Liebow, Susan Flaker, Greg Griffin, Josh Grabow, Matt Winans, Lynn Young, Cole Davidson, Jonathan Fransen, Alissa Smith, and Molly Driscoll

Information for Discussion:

Hy-Vee Pharmacy Fulfillment Center (4016) Des Moines, IA
Jonathan Fransen
Hy-Vee Pharmacy Fulfillment Center's 2020 Q1 Error Report
Reviewed

Meeting Appointments:

10:00

PharMerica Fridley
Blair Miller 261548-018
to allow a greater number of permitted first dose and emergency medications in the RxNow utilized as an e-kit

Approved - One Year

On condition that you follow your approved policies and procedures. Any policy and/or e-kit content changes are to be highlighted and submitted for Board approval prior to implementation

10:30

See Abbott Northwestern Hospital Pharmacy in the "Deferred to the Board" section.

11:00

Omnicare - Minnesota Brooklyn Center
Alison Sinclair 261366-023
to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist on site

Denied

Resubmit policies and procedures to include workflow and accountability for each step of the dispensing process for sterile and non-sterile compounded prescriptions

Omnicare - Minnesota

Alison Sinclair

Brooklyn Center

261366-027

policy review of unique identifiers for OmniDX dispensing system

Not Approved

Resubmit policies and procedures to explain assigned work stations, include procedures for logging off when staff leave their work stations, any disciplinary actions related to work station security, and to shorten the auto log-off for inactivity to less than 15 minutes. You should also include workflow and accountability for each step of the dispensing process for sterile and non-sterile compounded prescriptions

11:30

Mayo Clinic Hosp - Rochester, St. Mary's Campus Phcy

Ryan Anderson

Rochester

201162-013

to allow the pharmacy to utilize a non-contiguous, secure, monitored warehouse storage space for potential emergency pandemic/mass casualty drugs for Mayo employees and their family members

Approved - Indefinitely

On condition that the pharmacist-in-charge remains the same and that you follow your approved policies and procedures

Mayo Clinic Hosp - Rochester, St. Mary's Campus Phcy

Ryan Anderson

Rochester

201162-019

to allow the pharmacy to license and utilize a non-contiguous space for the storage of medications and supplies

Denied

Resubmit detailed policies and procedures related to the room's temperature and humidity monitoring, scope of products stored in this room, and include distance from the main pharmacy

Mayo Clinic Pharmacy Northeast

Randall Roggow

Rochester

262409-002

to allow the use of the scanned image to verify and check prescription validity

Approved - Indefinitely

Mayo Clinic Pharmacy-Northwest

Paul Heim

Rochester

261542-002

to allow the use of the scanned image to verify and check prescription validity

Approved - Indefinitely

MCHS - Albert Lea Hospital Pharmacy
Ross Martinson

Albert Lea
200439-006

to allow two certified pharmacy technicians to waste controlled substances, instead of two licensed individuals

Denied

Your policies and procedures are generic in nature and lacking completeness. The procedures would need to detail out everything that the pharmacy staff needs to know in order to perform the wasting process well and with consistency. It appears that critical steps and information are not included or explained in detail within the policies, including, but not limited to, defining designated areas, the technicians' roles, and the frequency and testing manner of assays are not clear

MCHS - Austin Hospital Phcy
Bradley Bachmeier

Austin
264086-004

to allow two certified pharmacy technicians to waste controlled substances, instead of two licensed individuals

Denied

Your policies and procedures are generic in nature and lacking completeness. The procedures would need to detail out everything that the pharmacy staff needs to know in order to perform the wasting process well and with consistency. It appears that critical steps and information are not included or explained in detail within the policies, including, but not limited to, defining designated areas, the technicians' roles, and the frequency and testing manner of assays are not clear

MCHS - Cannon Falls
Susan Flaker

Cannon Falls
265478-002

to allow two certified pharmacy technicians to waste controlled substances, instead of two licensed individuals

Denied

Your policies and procedures are generic in nature and lacking completeness. The procedures would need to detail out everything that the pharmacy staff needs to know in order to perform the wasting process well and with consistency. It appears that critical steps and information are not included or explained in detail within the policies, including, but not limited to, defining designated areas, the technicians' roles, and the frequency and testing manner of assays are not clear

MCHS - Lake City Hospital Phcy
Kelly Kennedy

Lake City
261637-005

to allow two certified pharmacy technicians to waste controlled substances, instead of two licensed individuals

Denied

Your policies and procedures are generic in nature and lacking completeness. The procedures would need to detail out everything that the pharmacy staff needs to know in order to perform the wasting process well and with consistency. It appears that critical steps and information are not included or explained in detail within the policies, including, but not limited to, defining designated areas, the technicians' roles, and the frequency and testing manner of assays are not clear

MCHS - Red Wing
Brian Kennedy

Red Wing
265477-002

to allow two certified pharmacy technicians to waste controlled substances, instead of two licensed individuals

Denied

Your policies and procedures are generic in nature and lacking completeness. The procedures would need to detail out everything that the pharmacy staff needs to know in order to perform the wasting process well and with consistency. It appears that critical steps and information are not included or explained in detail within the policies, including, but not limited to, defining designated areas, the technicians' roles, and the frequency and testing manner of assays are not clear

MCHS - Austin Hospital Phcy
Bradley Bachmeier

Austin
264086-001

to allow remote pharmacy after hours order review and entry of physician medication orders by Mayo Clinic Health System - Austin Hospital Pharmacy for Mayo Clinic Health System - Albert Lea, Cannon Falls, Lake City, and the new addition of Red Wing when the hospital pharmacies are closed after normal business hours of operation

Approved - 6 Months

On condition that there is adequate pharmacist coverage for the additional workload. Additional conditions listed in the letter of 07/01/2020

The provided after-hours service cannot be used to reduce the present hours or staff of the pharmacy that is being serviced, or to prevent needed expansion of hours. Provide the current level of staffing of the receiving pharmacy, including pharmacist full time equivalents, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced by the Hub Pharmacy

MCHS - Albert Lea Hospital Pharmacy
Ross Martinson

Albert Lea
200439-004

to allow remote pharmacy after hours order review and entry of physician medication orders by Mayo Clinic Health System - Austin Hospital Pharmacy for MCHS - Albert Lea Hospital when the hospital pharmacy is closed after normal business hours of operation

Approved - 6 Months

Conditions listed in the letter of 07/01/2020

The provided after-hours service cannot be used to reduce the present hours or staff of the pharmacy that is being serviced, or to prevent needed expansion of hours. Provide the current level of staffing of the receiving pharmacy, including pharmacist full time equivalents, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced by the Hub Pharmacy

MCHS - Cannon Falls
Susan Flaker

Cannon Falls
265478-001

to allow remote pharmacy after hours order review and entry of physician medication orders by Mayo Clinic Health System - Austin Hospital Pharmacy for Mayo Clinic Health System - Cannon Falls when the hospital pharmacy is closed after normal business hours of operation

Approved - 6 Months

Conditions listed in the letter of 07/01/2020

The provided after-hours service cannot be used to reduce the present hours or staff of the pharmacy that is being serviced, or to prevent needed expansion of hours. Provide the current level of staffing of the receiving pharmacy, including pharmacist full time equivalents, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced by the Hub Pharmacy

MCHS - Lake City Hospital Phcy
Kelly Kennedy

Lake City
261637-003

to allow remote pharmacy after hours order review and entry of physician medication orders by Mayo Clinic Health System - Austin Hospital Pharmacy for Mayo Clinic Health System - Lake City when the hospital pharmacy is closed after normal business hours of operation

Approved - 6 Months

Conditions listed in the letter of 07/01/2020

The provided after-hours service cannot be used to reduce the present hours or staff of the pharmacy that is being serviced, or to prevent needed expansion of hours. Provide the current level of staffing of the receiving pharmacy, including pharmacist full time equivalents, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced by the Hub Pharmacy

MCHS - Red Wing
Brian Kennedy

Red Wing
265477-001

to allow remote pharmacy after hours order review and entry of physician medication orders by Mayo Clinic Health System - Austin Hospital Pharmacy for Mayo Clinic Health System - Red Wing when the hospital pharmacy is closed after normal business hours of operation

Approved - 6 Months

Conditions listed in the letter of 07/01/2020

The provided after-hours service cannot be used to reduce the present hours or staff of the pharmacy that is being serviced, or to prevent needed expansion of hours. Provide the current level of staffing of the receiving pharmacy, including pharmacist full time equivalents, with the variance request. Include the anticipated or estimated number of prescriptions that will be serviced by the Hub Pharmacy

1:00

Coborns Central Support Pharmacy #9942

Sauk Rapids

Justin Dullinger

265841-001

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist on site or from any approved MN located Coborn's or Cashwise retail pharmacy

Deferred to the Board

Deferred with the licensee's approval for discussion

Coborns & Cash Wise Pharmacies

34 Locations

Matt Winans

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist on site or from Coborn's Central Support Pharmacy #9942

Deferred to the Board

Deferred with the licensee's approval for discussion

1:30

Hy-Vee Health Market Rx (7064)

Pine Island

Patrick McDonough

265808-007

to allow an exemption from the Board's rule regarding direct supervision of supportive personnel - revisions sent 5/29/20

Approved - One Year

On condition that Kasson has a copy of the related policies and procedures with additional conditions listed in the letter of 07/01/2020

Hy-Vee Pharmacies

36 Locations

Cole Davidson

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification for new or refillable prescriptions by more than one pharmacist within your own facility - revision sent 5/10/19 to include more than one pharmacist from any of the approved 36 MN Hy-Vee locations

Approved - Two Years

Hy-Vee Pharmacies

36 Locations

Cole Davidson

to allow an exemption from the Board's rule regarding central service label requirements

Approved - Two Years

2:00

Hy-Vee Pharmacy Fulfillment Center (4016)
Jonathan Fransen

Des Moines, IA
264241-001

policy review of central fill - revisions sent 5/29/20 to ship prescription drugs directly to a patient's home on behalf of the originating retail pharmacy

Deferred to the Board

Deferred with the licensee's approval for discussion

Hy-Vee Pharmacy Fulfillment Center (4016)
Jonathan Fransen

Des Moines, IA
264241-005

to allow the originating retail pharmacy to provide the patient counseling on behalf of the Hy-Vee Pharmacy Fulfillment Center (4016) for prescriptions that are shipped directly from the Fulfillment Center to the patient's home

Deferred to the Board

Deferred with the licensee's approval for discussion

Policy Reviews:

Fairview Specialty Services Pharmacy
Jacob Hansen

Minneapolis
262542-021

policy review of unique identifiers for an OptiFill II prescription medication dispensing system (auto log off)

Approved

Fairview Pharmacies
Sarah Brown

34 Locations

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist, from any approved licensed Fairview outpatient pharmacy in Minnesota

Approved - Three Years

Hopkins Center Drug
Chris Beckmann

Hopkins
265922-001

policy review of a ScriptPro SP200 prescription dispensing system

Approved

As a reminder, USP 800 prohibits antineoplastics from being in automation

North Memorial Health Pharmacy - Robbinsdale
Paul Krogh

Robbinsdale
200751-009

policy review of bar-code medication validation for the restocking of automated distribution machines

Not Approved

Resubmit policies and procedures to address all elements in MN Rule 6800.2600 and the guidance document for, "Use of Medication Bar-Code Scanning During Stocking of ADDS in Hospital"

Park Nicollet Pharmacy #87017

St. Louis Park

James Bychinski

266080-001

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist on site

Approved - Two Years

With your next renewal, remove all references to HealthPartners pharmacies

Park Nicollet Pharmacy #87017

St. Louis Park

James Bychinski

266080-002

policy review of unique identifiers for RDAC

Approved

New Variances:

Essentia Health Hibbing Pharmacy

Hibbing

Joseph Seeba

261240-004

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist, between Essentia Health Hibbing Pharmacy and Infusion Center Pharmacy for adult and pediatric patients receiving treatment at Essentia Health Hibbing Infusion Center

Denied

Resubmit policies and procedures to meet all elements of the guidance documents. You must also submit policies to obtain Board approval for central service (MN Rule 6800.4075)

Infusion Center Pharmacy

Duluth

Paul Schillo

261241-002

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist, between Essentia Health Hibbing Pharmacy and Infusion Center Pharmacy for adult and pediatric patients receiving treatment at Essentia Health Hibbing Infusion Center

Denied

Resubmit policies and procedures to meet all elements of the guidance documents. You must also submit policies to obtain Board approval for unique identifiers (MN Rule 6800.0100) and central service (MN Rule 6800.4075)

Goodrich Pharmacy, Inc.
Cory Middendorf
to allow an exemption from the Board's rule regarding space
Approved - Indefinitely
On condition that there is appropriate space for the volume

Anoka
Pending

Goodrich Pharmacy, Inc.
Cory Middendorf
to allow an exemption from the Board's rule regarding equipment and having a sink within the pharmacy

Anoka
Pending

Denied

The supporting documents provided do not substantiate that the variance request is equal or superior to those prescribed in the Rule and the request is not consistent with current standards of practice for dispensing pharmacies

Option Care
Alexandra Demello
to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist on site

Roseville
262204-002

Denied

Resubmit policies and procedures to meet all elements of the guidance document. You must also submit policies to obtain Board approval for unique identifiers (MN Rule 6800.0100)

Option Care
Daniel Dixon
to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, for new or refillable prescriptions, by more than one pharmacist on site

Sauk Rapids
263567-003

Denied

Resubmit policies and procedures to meet all elements of the guidance document. You must also submit policies to obtain Board approval for unique identifiers (MN Rule 6800.0100)

Seip Prescription Shoppe
Scott Miller
to allow the pharmacy to provide an emergency kit to MEnD for the treatment of inmates at the Wadena County Jail after business hours

Wadena
263046-002

Denied

Resubmit with related policies and procedures

Renewal Variances:

Fairview Compounding Pharmacy
Landen Sanderson

Minneapolis
262526-004

to allow Fairview Home Infusion Pharmacy to share select space and equipment with Fairview Compounding Pharmacy - (revisions sent 10/4/19 to have a variance to not have floor to deck wall between the two pharmacies)

Approved - Three Years

Fairview Home Infusion
Emma Huepfel

Minneapolis
262531-002

to allow Fairview Home Infusion Pharmacy to share select space and equipment with Fairview Compounding Pharmacy - (revisions sent 10/4/19 to have a variance to not have floor to deck wall between the two pharmacies)

Approved - Three Years

Fairview Lakes Health Services Pharmacy
Mark Nelson

Wyoming
261510-013

to allow remote pharmacy after hours order review and entry of physician medication orders by Fairview Lakes Health Services Pharmacy for Osceola Medical Center located in Osceola, WI when the hospital pharmacy is closed from normal business hours of operation - revisions sent on 4/13/18 to include the WI sites in Ashland, Hayward, and Grantsburg

Approved - 6 Months

Conditions listed in the letter of 07/01/2020

With your next renewal, submit data for order review and census related to Fairview Lakes Health Services Pharmacy patients during the time that they are reviewing orders for the 4 Wisconsin sites

Deferred to the Board:

Abbott Northwestern Hospital Pharmacy
Kristine Gullickson

Minneapolis
201004-017

to allow the pharmacy to utilize a non-contiguous storage space in an infusion center pharmacy satellite

Deferred to the Board

The Committee recommends a deferral with the licensee's approval

Allina Health Heart Hospital Pharmacy
Amanda Elliott

Minneapolis
262587-014

to allow the storage and distribution of Allina Health Phillips Eye Institute's 3 compounded fortified antibiotic preparation

Deferred to the Board

The Committee recommends a two year approval

Allina Health Heart Hospital Pharmacy
Amanda Elliott

Minneapolis
262587-015

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, limited to 3 fortified antibiotic preparations of compounded drugs, by more than one pharmacist from Allina Health Phillips Eye Institute or Allina Health Heart Hospital

Deferred to the Board

The Committee recommends a two year approval

Allina Health Phillips Eye Institute Pharmacy
Jay Dahlstrom

Minneapolis
262251-011

to allow Allina Health Heart Hospital to possess three different compounded antibiotic ophthalmic formulations preparations of Allina Health Phillips Eye Institute's compounded drugs

Deferred to the Board

The Committee recommends a two year approval

Allina Health Phillips Eye Institute Pharmacy
Jay Dahlstrom

Minneapolis
262251-012

to allow the separation of the prescription dispensing process including verification, drug utilization review (DUR) and/or certification, limited to 3 fortified antibiotic preparations of compounded drugs, by more than one pharmacist from Allina Health Phillips Eye Institute or Allina Health Heart Hospital

Deferred to the Board

The Committee recommends a two year approval

Cardinal Health Pharmacy Services LLC
Timothy Larson

Westmont, IL
263447-001

to allow remote pharmacy after hours order review and entry of physician medication orders by Cardinal Health in Westmont, IL for the Sanford Hospitals located in Westbrook, Tracy, Jackson, Canby, Worthington, Wheaton, Luverne, and Thief River Falls (and Behavioral Health), Ortonville Area Health Service, Murray County Memorial Hospital, Windom Area Hospital, Winona Health Services Hospital, Riverview Healthcare, Kittson Memorial Healthcare Center, Perham Health Hospital, Mahanomen Health Center, Olivia Hospital & Clinic - Pharmacy, Prairie Ridge Hospital, Lake Region Healthcare, United Hospital District, Inc., Carris Health – Redwood, Carris Health Rice Memorial Hospital, and the CentraCare Health Hospitals located in Sauk Centre, Paynesville, Long Prairie, Melrose, and Monticello when the hospital pharmacies are closed from normal business hours of operation and Sanford Pharmacy Detroit Lakes Outpatient pharmacy orders for their Surgery Center to assist before and during the first hour of the pharmacy's operation

Deferred to the Board

The Committee recommends a one year approval on condition that the coverage for Sanford Pharmacy Detroit Lakes is only for the after hours coverage and during the first hour the pharmacy is open M-F. Additional conditions listed in the letter of 07/01/2020

With your next renewal, you must cite MN Rule 6800.7520 or the submission may be rejected

Sanford Pharmacy Detroit Lakes
Julie Kauffman

Detroit Lakes
263507-002

to allow remote pharmacy services after hours and during the first hour of the pharmacy's daily operation for order review and entry of physician medication orders by Cardinal Health in Westmont, IL for Sanford Pharmacy Detroit Lakes Surgery Center when the outpatient pharmacy is closed from normal business hours of operation

Deferred to the Board

The Committee recommends a one year approval on condition that the coverage for Sanford Pharmacy Detroit Lakes is only for the after hours coverage and during the first hour the pharmacy is open M-F. Additional conditions listed in the letter of 07/01/2020

Cardinal Health Associated Pharmacies
Timothy Larson

27 Locations

to allow remote pharmacy after hours order review and entry of physician medication orders by Cardinal Health in Westmont, IL for Sanford Westbrook Medical Center when the hospital pharmacy is closed from normal business hours of operation

Deferred to the Board

The Committee recommends a one year approval with conditions listed in the letter of 07/01/2020